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(54) Therapeutic nasal drops containing sulphonamides

(57) Nose drops for treating local nasal infections contain a sulphonamide, preferably sodium sulphacetamide, in aqueous solution. The solutions may also contain a sympathomimetic nasal decongestant and an anti-inflammatory corticosteroid.

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COMPOSITIONS OF SOME THERAPEUTIC ADVANTAGE PREPARED FROM A COMBINATION
OF AN ANTISEPTIC AGENT WITH A SYMPATHOMIMETIC COMPOUND IN THE FORM OF
NOSE DROPS

This invention relates to a novel composition of therapeutic significance prepared from a combination of an antiseptic agent with a sympathomimetic compound in the form of nose drops.

Previously, the treatment of notoriously reoccurring ailments such as rhinitis, sinusitis, hay fever, infected inflammatory nasal conditions, nasal congestion associated with infection and the nasal carriage of staphylococci has generally consisted of long term systemic oral antibiotic courses which are unpracticable due to the long term and frequent therapeutic dosages of antibiotic that need to be taken. Many people are known to suffer side effects when on frequent antibiotic courses and resistance by bacteria to long term oral administration of antibiotics is well documented.

It is therefore a principal object of this invention to provide a locally acting product of therapeutic significance prepared from an antiseptic agent in combination with sympathomimetic compounds with or without the addition of corticosteroid anti-inflammatory agents in the form of nose drops for the treatment of rhinitis, sinusitis, hay fever, infected inflammatory nasal conditions, nasal congestion associated with infection and the nasal carriage of bacteria.

Accordingly, the above object has been achieved by using the antiseptic agent sodium sulphacetamide in concentrations of 1 - 20 % with or without xylometazoline hydrochloride or oxymetazoline hydrochloride or tetrahydrozoline hydrochloride or tramozoline hydrochloride or any other sympathomimetic compounds in a concentration of 0.001 % to 2.0 %. The preferable concentration of the antiseptic agent is between 4.0 and 7.0 %. Sodium sulphacetamide is an antiseptic that has commonly been used in eye drops with an undisputed safety record for the last forty years. These eye drops have contained sodium sulphacetamide in a concentration of 10.0 to 30.0 % in an aqueous solution.

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The inclusion of a sympathomimetic compound in the formula is due to its action as a vasoconstrictor. It helps to reduce inflammation and lowers congestion in nasal mucous membranes. The percentage preferred in this formula is about 25.0 % of the standard naphazoline nasal drop concentration. Weaker strengths appear to provide a more sustained decongestant effect and also appear to minimise the rebound effect.

In this invention the preferred strength of sulphacetamide is 4.0 to 7.0 % which is not sufficient to irritate the nasal mucosa. Sulphacetamide is an effective bacteriostatic agent against a wide range of Gram-negative and Gram-positive bacteria.

The following examples illustrate the invention and the advantages thereof. These examples are given by way of illustration only, and are not to be construed as limiting the invention in scope or in spirit, as many modifications will be apparent from this disclosure to those skilled in this art.

Example 1:

Sodium sulphacetamide	6.0 %
Xylometazoline hydrochloride	0.025 %

Example 2:

Sodium sulphacetamide	6.0 %
Oxymetazoline hydrochloride	0.0125 %

Example 3:

Sodium sulphacetamide	6.0 %
Tramazoline hydrochloride	0.025 %

Example 4:

Sodium sulphacetamide	6.0 %
Tetrahydrozoline hydrochloride	0.025 %

Example 5:

Sodium sulphacetamide	6.0 %
Antazoline sulphate	0.5 %
Naphazoline hydrochloride	0.1 %

Example 6:

Sodium sulphacetamide	6.0 %
Naphazoline hydrochloride	0.05 %
Betamethasone	0.1 %

Example 7:

Sodium sulphacetamide	6.0 %
Betamethasone	0.1 %

CLAIMS

1. Products for the treatment of rhinitis, sinusitis, hay fever, infected inflammatory nasal conditions, nasal congestion associated with infection derived from sulphonamide antiseptic agent with or without one or more sympathomimetic agents in the form of nose drops.
2. Products as in Claim 1 in which the antiseptic agent is sodium sulphacetamide in a concentration of 1.0 to 20.0 % in combination with sympathomimetic agent(s) in a concentration of 0.001 to 1.0 %.
3. Products as in Claims 1 & 2 to which a steroid compound is added in concentrations of 0.01 to 5.0 %.
4. Products as in Claim 1 comprising of any soluble sulphonamide compound in a concentration of 1.0 to 20.0 % in combination with any sympathomimetic agent including xylometazoline hydrochloride, oxymetazoline hydrochloride, tramazoline hydrochloride, naphazoline hydrochloride, antazoline sulphate and tetrahydrozoline hydrochloride in a concentration of 0.001 to 2.0 %.
5. Products as in Claim 1 derived from sodium sulphacetamide in a concentration of 1.0 to 20.0 % without the addition of a sympathomimetic agent.